IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

In the Application of:
John F. Wironen *et al.*

Serial No.: 09/897,728

Filed: July 3, 2001

For: "Quantitative In Vitro Bone Induction Assay"

Group Art Unit: 1646

Examiner: Not yet assigned

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date:

January 19, 2004

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RESPONSE TO RESTRICTION UNDER 35 USC § 121

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The Applicants hereby respond to the restriction of invention under 35 U.S.C. § 135 that was imposed in the Official communication of 09/30/03, for which a response was due 10/30/03, now extended three months to 01/30/04.

A document is accompanied by a check in the amount of $950 to cover the fee under 37 C.F.R. § 1.17(a)(3). In the event that any additional fees are due as a result of filing this paper, the Assistant Commissioner is hereby authorized to charge deposit account 13-0017 in the name of McAndrews Held & Malloy, Ltd.

The Patent Office has imposed an 8-way restriction requirement on claims 1-36 of the present invention. In response, the Applicants respectfully traverse the restriction but elect to prosecute the invention of Group I, claims 1-23, directed to a method for quantifying an osteoinductive potential of a collection of implant material. In traversing this restriction, the Applicants respectfully submit that claim 31 is properly a member of Group I. In particular, claims 1-23 are directed to an *in vitro* method for quantifying an osteoinductive potential of a collection of implant material, whereas, claim 31 is directed to the natural consequence (whereby clause) of the method of claim 1, which is the reduction in the need to perform *in vivo* assays involving animal sacrifice. The preamble of claim 1 has been amended, consistent with step (b) to clarify the *in vitro* nature of the assay.

If the Applicants elect to prosecute Group I, the Patent Office imposes the further restriction stating "please select one of the bone implant material types or a specific combination of two types listed in claim 3, so that initial examination may proceed." [Official Communication at page 3.] The Applicants respectfully traverse the restriction, but elect to prosecute the "allograft" material from claim 3, which is "cortical" or "cancellous" bone or a "combination thereof." In traversing this basis for rejection, the Applicants respectfully submit that the assay is equally as applicable to "autograft" bone and "xenograft" bone. The designation of the bone in the assay as "auotgraft," allograft" or "xenograft" is dependent upon the **intended** recipient of the bone and has nothing to do with the assay itself. For example, when the assay of claim 1 is performed on a single specimen of bone, the same bone specimen could be autograft (such as when the donated bone specimen gets implanted back into the donor), allograft (such as when the donated specimen gets implanted in the donor's son), and xenograft (such as when the donated specimen gets implanted in the donor's dog). Therefore, the mental intent of the physician on the use of the assayed bone after the assay should not impose a restriction on the assay itself. Moreover, the Patent Office is not required to conduct a separate search based upon the intended recipient of the donated bone. For all these reasons, the claimed assay should not be restricted to bone that is "auotgraft," allograft" or "xenograft."

The Patent Office next contends that if Group I is selected, then the Applicants are required to "select one of the osteoinductive/osteogenic factors or a **combination of two** factors listed in claims 13-15, so that initial examination of the application may proceed."

[Official Communication at page 3; emphasis added in bold.] In response, it is noted that claims 13-15 comprise a plurality of factors. From claim 13, the Applicants elect the combination of the two factors "bone morphogenic proteins" and "tissue growth factors".